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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,718

06/20/2003

Leonel Merwe van Zyl

297/167

5862

25297

7590

10/06/2006

JENKINS, WILSON, TAYLOR & HUNT, P. A.

3100 TOWER BLVD

SUITE 1200

DURHAM, NC 27707

EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/600,718

Applicant(s)

VAN ZYL, LEONEL MERWE

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The applicant's response filed 9/5/06 to the Office action has been entered. Claims 1-20 are pending.

#### *Election/Restrictions*

1. Applicant's election without traverse of Group II, claims 17-20 in the reply filed on 9/05/06 is acknowledged. Since the response does not have a specific argument for the restriction requirement the election is considered without traverse.
2. Claims 1-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/5/06.

#### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - a. Claim 18 is vague and indefinite because it is unclear what is meant by the phrase "the labeling mix is a 5X mixture". Does it mean that the mixture is 5 times diluted or 5 times concentrated? Clarification is required.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoki et al. (US 2002/0064782, issued May 30, 2002).

Shinoki et al. disclose a fluorescent nucleotide, which is useful for efficient labeling of nucleic acids (See pg. 1, [0010]). The invention provides a process of preparing fluorescence-labeled nucleic acids, which comprises the step of conducting a reaction of the synthesis of nucleic acid by using nucleic acid synthetase, a nucleic acid as a template, and the fluorescent nucleotide of the present invention (See pg. 6[0059]). The nucleic acid synthetase is Klenow enzyme (See pg. 6, [0060]). The random prime method is one of the methods for labeling DNA in which hexanucleotide primer is used (See pg. 6, [0062]). The labeling mixture comprises dATP, dCTP, dGTP and dTTP and at least one of a fluorescently labeled nucleotide selected from the group consisting of dUTP-Cy3<sup>TM</sup> and dUTP-Cy5<sup>TM</sup> (See pg. 11, [0106]). The fluorescent nucleotide of the invention can be supplied in the form of a kit for detecting nucleic acid (See pg. 7 [0072]).

Shinoki et al. do not disclose the kit, which is for fluorescently labeling a nucleic acid including the components recited in the instant claims. However, Shinoki et al. disclose that types of reagents to be contained in the kit can be appropriately selected according to the purpose of the kit such reagent may include the fluorescent nucleotide, nucleic acid synthetase, buffer as

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well as a mixture of one or more (preferably four) non-fluorescent nucleotides, purified water or the like. The kit can further contain primers (See pg. 7, [0072]).

One of ordinary skill in the art would have been motivated to make the kit for fluorescently labeling a nucleic acid including the components recited in the instant claims as suggested by Shinoki et al. Moreover, it was also routine practice in the art to make a kit including all the components as needed for conveniently performing a method. It would have been prima facie obvious to make the kit for fluorescently labeling a nucleic acid

Shinoki et al. also do not disclose the ratio of dATP to dCTP to dGTP to dTTP to dUTP-Cy3 or dUTP-Cy5 is 8:8:8:1:1 as recited in claims 17 and 18.

Shinoki et al. disclose the concentration of dATP (500uM), dCTP (500uM), dGTP (500uM) to dTTP (200uM), dUTP-Cy3 (100uM) or dUTP-Cy5 (100uM) (See pg. 11, [0106])

One of ordinary skill in the art would have been motivated to optimize the ratio of dATP to dCTP to dGTP to dTTP to dUTP-Cy3 or dUTP-Cy5 to be higher or lower than the ratio used in the method of Shinoki et al. because the optimization of the experiment condition, for example, the concentration of the reagent was routine practice in the art at the time of the instant invention filed. It would have been prima facie obvious to make the kit for fluorescently labeling a nucleic acid with the ratio of dATP to dCTP to dGTP to dTTP to dUTP-Cy3 or dUTP-Cy5 as recited in claims 17 and 18.

### Summary

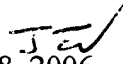
7. No claims are allowable.

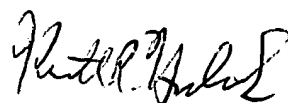
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung   
September 28, 2006

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

10/2/06